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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,828	11/20/2001	Paul Luther Skatrud	X-11766B	8530
25885	7590	04/25/2003		
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER	
			BASKAR, PADMAVATHI	
		ART UNIT	PAPER NUMBER	
		1645		

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,828	SKATRUD ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 7 and 10-14 is/are pending in the application.
 - 4a) Of the above claim(s) 7 and 12-14 is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 10-11 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) 7 and 10-14 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
 - 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) Interview Summary (PTO-413) Paper No(s) 9 /
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

1 Applicant's preliminary amendment filed on 6/18/2001 has been entered. Claims 1-6 and 8-9 have been canceled. Claim 7 has been amended. Applicant requests the office to cancel claim 15 (see Interview summary # 9). However, there is no pending claim 15 in the application. Claims 7, 10-14 are pending in the application.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Applicant is advised to amend the specification, page 1, line 3 to recite priority application and the corresponding U.S.Patent. For example: This application is a division of the U.S.Application 09/328,320, now U.S.Patent 6,228,615 which is a divisional of U.S Application 08/996,545, now U.S.Patent 5, 928, 898 ".

Applicant is also advised to update the status of the U.S.Application 08/111680 on page 11 in the specification.

It is noted that claims 10-11 get priority as of the filing date of the present application because the specification does not enable (see Paragraph # 15) the presently claimed invention as of the filing date of the priority documents.

Drawings

3. No drawings have been submitted in this application.

Information Disclosure Statement

4. Information Disclosure Statement filed on 1/11/01, Paper # 5 is acknowledged and a signed copy is attached with this action.

Election/Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 10,11 drawn to a method for determining the fungal MDR inhibition activity, classified in class 435, subclass 7.1
 - II. Claim 14 drawn to a method for identifying anti-fungal compound, classified in class 435, subclass 7.1
 - III. Claim 12, drawn to a protein, classified in class 530, subclass 350
 - IV. Claim 13 drawn to a strain of Aspergillus, which does not produce the atrD protein, classified in class 435 subclass 254.11.
 - V. Claim 7 drawn to an isolated DNA classified in class 536, subclass 23.6
6. The inventions are distinct, each from the other because of the following reasons:
- Invention III, IV and V are two different products namely protein, strain of Fungi and a DNA molecule respectively. These products are different to each other structurally, functionally and biochemically because protein is made of only amino acids, DNA contains nucleic acid molecules and a strain of Aspergillus which is genetically altered organism belonging to Class Fungi.
- Inventions I and II are patentably distinct methods utilizing different reagents. Invention I requires a compound, which inhibits multi drug resistance activity and a fungal cell where as Invention II, requires a strain of Aspergillus and antifungal compound. Thus, these methods are different in utilizing different reagents, method steps and result in a different outcome.
7. Inventions III and I /II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product protein can be used in immunoaffinity chromatography methods for purifying antibodies.

Inventions IV and I/II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product a strain of fungi can be used for raising antibodies etc.

Inventions V and I/II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group V can be used to prepare hybrid clones of Aspergillus.

8. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not co-extensive, restriction for examination purposes as indicated is proper

9. During a telephone conversation with Miss. Tina Tucker on 2/10/03 a provisional election was made without traverse to prosecute the invention of group I, claims 10-11. Affirmation of this election must be made by applicant in replying to this Office action.

10. Claims 7, 12-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Claim Rejections - 35 USC § 112, second paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rejected as being vague and indefinite for the recitation of "capable of ". The expression "capable of " used in the claim renders the claim indefinite because the metes and bounds of the term "capable of " are unclear. In claim 10, the abbreviation "atrD" is used without definition upon its first appearance in the claims. Therefore, applicant is advised to amend the claim to recite "a vector which expresses a nucleic acid encoding a atrD protein as set forth in SEQ.ID.NO: 2."

In claim 10, the abbreviation "MDR" is used without definition upon its first appearance in the claims.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor or carrying out his invention.

15. Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to a method for determining the fungal Multiple Drug Resistance (MDR) inhibition activity of a compound which comprises (a) placing a cultured fungal cells, transformed with a vector capable of expressing atrD in the presence of (i) "an antifungal agent to which fungal cells are resistant but to which said cultured fungal cells are sensitive in their untransformed state (ii) " a compound suspected of possessing *A.nidulans MDR* inhibition activity"; and (b) "determining the fungal MDR inhibition activity of said compound by measuring the ability of antifungal agent to inhibit the growth of said fungal cells.

The specification teaches atrD Gene from *A.nidulans* as one of the Multiple Drug Resistance (MDR) Gene. The Specification also teaches cloning of a nucleic acid encoding atrD protein as set forth in SEQ.ID.NO: 2. However, the specification is silent in teaching any compound that inhibits the growth of fungal cells expressing a nucleic acid encoding a protein atrD (transformed) as set forth in SEQ.ID.NO: 2 and untransformed cells including *S.cerevisiae* as claimed. The specification does not teach the anti-fungal compounds to which untransformed yeast cells are sensitive and transformed cells are resistant in determining the fungal Multiple Drug Resistance (MDR) inhibition activity. The specification is silent in disclosing transformed cells that lack 500 base pairs at the N-terminus region and 500 base pairs at the C-terminus end and the correlating inhibitory activity of a compound on (see example 4) on these cells. With regard to gene disruption and gene replacement studies, the specification is totally silent in

disclosing the hypersensitive strains to antifungal compounds (see example 4) for determining the fungal Multiple Drug Resistance (MDR) inhibition activity. The specification provides no working examples demonstrating (i.e., guidance) the function for atrD or at least that it confers resistance to one or several anti-fungal agents. Further, what compounds and what concentrations would inhibit the MDR activity either completely or partially were not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Therefore, enablement for a method for determining fungal Multi Drug Resistance (MDR) inhibition activity of a compound using the claimed transformed vector which expresses a nucleic acid encoding a protein atrD as set forth in SEQ.ID.NO: 2 is considered unpredictable, requiring a specific demonstration of MDR inhibition activity of a compound using the claimed transformed vector which expresses a nucleic acid encoding a protein atrD as set forth in SEQ.ID.NO: 2. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

Status of Claims

16. Claims 10-11 are not allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.

4/1/03



MARK NAVARRO
PRIMARY EXAMINER